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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,874	02/08/2001	Michael Wassenegger	MPG-1 DIV-1	6565

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EXAMINER	
HELMER, GEORGIA L	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 11/20/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/782,874	WASSENEGGER ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-35,37,40,41,48 and 53-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-35,37,48 and 53-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *29-35,37,40,41,48,53-61 and 64-71* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *12*
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's restriction election, Paper No. 12, filed 3 September 2002. The Restriction and Election is reiterated as follows:

2. The Restriction to one of the following inventions is required under 35 U.S.C. 121:

VI. Claims 27, 28, 42, 43, and 46, drawn to drawn to transgenic animals. classified in class 800, subclass 8.

VII. Claims 44, 45, and 53-61, drawn to transgenic animal cells and nucleic acids, classified in class 435, subclass 325.

VIII. Claims 29-35, 37, 53-61, and 64-71 drawn to transgenic plants, plant cells, and plant tissue culture, and nucleic acids, wherein the DNA insert is in sense orientation, classified in class 800, subclass 278.

XII. Claims 53-61, drawn to drawn to an isolated DNA molecule and a bacterial or fungal host cell, classified in class 435, subclass 69.1.

XIII. Claims 29-35, 37, 48, 53-61, and 64-71, drawn transgenic plants, plant cells, and plant tissue culture, and nucleic acids, wherein the DNA insert is in antisense orientation classified in class 800, subclass 278.

XIV. Claims 29-35, 37, 53-61; and 64-71 drawn to transgenic plants, plant cells, and plant tissue culture, and nucleic acids, wherein reduction in polypeptide synthesis is by ribozyme inhibition, classified in class 800, subclass 278.

3. Claims 53-58 and 60 link(s) inventions VII, VIII and XII-XIV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 53-58 and 60. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Furthermore, in confirming Examiner's phone call of 12 August 2002, Claims 40, 41, 62, 63 will be examined with Group IX, claim 48 will be examined with Groups VIII, XIII and XIV, claim 50 will be examined with Group X, and claim 52 will be examined with Group XI.

Applicant elects Group VIII, claims 29-35, 37,48, 53-61, and 64-71 drawn to transgenic plants, plant cells, and plant tissue culture, and nucleic acids, wherein the DNA insert is in sense orientation, with traverse. Claims 29-35, 37,40, 41, 48, and 52-71 are pending. Claims 40, 41, 52, 62 and 63 are nonelected. Claims 29-35, 37,48, 53-61, and 64-71 are examined in the instant application. This restriction is made FINAL.

4. Claims 32 and 59 are objected to because the nonelected invention should be deleted from the claims.

Sequence Listing

5. Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

6. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 4, dated 8 February 2001, is attached to the instant Office action.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 29-35, 37,48, 53-61, and 64-71 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,218,142. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species claims of patent 6,218,142 renders the genus claims of the instant application obvious. The host cell of 6,218,142, which may be a plant cell, makes obvious the transgenic plant cell (claim 29 of instant case) which is transformed with SEQ ID NO: 1.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 35 and 37 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Seeds and propagules of transgenic plants have undergone Mendelian segregation and, unless grown under selective conditions, may not have received the transgene. This would result in wild-type seed, which is a product of nature.

Claim Rejections - 35 USC § 112 second

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-35, 37, 48, 53-61, and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 29 (a), 31, 32 are unduly alternative in reciting "and/or" on one or more occasions; choosing one of the other is suggested.
- Claim 29 (b) recites a "template" serving as a "template", which is confusing. Reciting a "first" and "second" template is suggested. Furthermore "said" nucleic acid lacks antecedent basis.
- In claims 29 and 31, the meaning of the parentheticals is unclear. Are these further limitations or examples?
- In claim 35, "harvestable" parts, implies that some parts are not harvestable". Which plant parts are which?
- In claim 53 (c), it is unclear what encodes? "a part" of (a) or (b)? Or one of the DNA sequences of (a) or (b)?
- In claim 71, "the nucleic acid comprising" ..."the nucleic acid" is confusing. Maybe the second "the" should be "said".

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112-1 - Written Description

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 29-35, 37, 48, 53-61, 64-69 and 71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to sequences that are at least 60% identical to SEQ ID NO: 1 that encodes a protein at least 60% identical to SEQ ID NO: 2 or to conservative variants thereof that have RdRP enzymatic activity. However, the specification does not disclose what structural features would be conserved in the claimed sequences that would result in the claimed enzyme activity. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

Claim Rejections - 35 USC § 112-Enablement

13. Claims 29-35, 37, 48, 53-61, 64-69 and 71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims to a nucleic acid of SEQ ID NO: 1 or a nucleic acid encoding SEQ ID NO: 2, which has RdRP enzymatic activity, does not reasonably provide enablement for any sequences that are at least 60% identical to SEQ ID NO: 1 that encodes a protein at least 60% identical to SEQ ID NO: 2 or to conservative variants thereof that have RdRP enzymatic activity. The specification, while being enabling for claims to a nucleic acid of SEQ ID NO: 1 or a nucleic acid encoding SEQ ID NO: 2, which has RdRP enzymatic activity, does not reasonably provide enablement for a SEQ ID NO: 1 or a nucleic acid encoding SEQ ID NO: 2, where that nucleic acid (presence/transcription/expression) causes a reduction in synthesis of a RdRP. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification sets forth a gene represented as SEQ ID NO: 1. However, the specification does not indicate what structural or functional properties of SEQ ID NO: 1 would represent an RdRP gene other than that of SEQ ID NO: 1 encoding SEQ ID NO: 2.

Sequence homology is not sufficient to predict function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions" (the last sentence of the first paragraph of page 248). Doerks

also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). In addition, Smith et al (Nature Biotechnology 15:1222-1223, November 1997) teach that "there are numerous cases in which proteins of very different functions are homologous" (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that "most homologs must have different molecular and cellular functions" (see the second full paragraph of the second column of page 132, for example). Furthermore, Borks (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

Applicant claims a reduction in synthesis of an RdRP in a plant cell, resulting from SEQ ID NO: 1 or a nucleic acid encoding SEQ ID NO: 2 or any other sequence. Applicant does not teach a reduction in synthesis of an RdRP in a plant cell, resulting from SEQ ID NO: 1 or a nucleic acid encoding SEQ ID NO: 2 or from any other sequence. Mechanisms for RdRP synthesis, regulation and degradation are not clear (Ahlquist, Science 296, pages 1270-1273, May 2002, p 1272 1st and 2nd columns, and p 1273, final paragraph). The biological functions of cellular RdRPs are not known (Schiebel, et al, Plant Cell, vol. 10, December 1998, pages 2087-2101, p 2097, final paragraph). Whereas one of skill in the art can readily insert nucleic acids into plant cells, guidance is required as to what sequences under what conditions would result in reduction of synthesis of RdRP synthesis. To require one skilled in the art to make changes by random experimentation without guidance as to how to eliminate inoperable

embodiments, other than by trial and error is an invitation to experiment requiring excessive and undue experimentation.

Therefore it would require undue experimentation to identify other polynucleotides which would have the desired enzymatic activity since specific motifs and structural features are not described; the lack of working examples of other sequences encompassed by the claims; the lack of working examples of any reduction of RdRP synthesis; the breadth of the claims (any plant, any nucleic acid, any condition which leads to any reduction of RdRP synthesis, any RdRP); and the unpredictably of the art, to enable the invention as commensurate in scope with the claims.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 29-35, 37, 53-61 and 64-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischhoff, et. al, US 5,495,071, issued February 27, 1996.

The claims are drawn to nucleic acids encoding polypeptides having RdRP activity, related nucleic acids and parts thereof, transgenic plant cells, transgenic plants, and propagation material. The Office interprets "a part" of a DNA sequence to be a single base.

Fischoff teaches a tomato plant transgenic for a Bacillus thuringensis toxin protein gene (Abstract). The tomato plant of Fischhoff inherently has a tomato RdRP coding sequence, and since it is transgenic for a heterologous gene, anticipates the claimed invention. Fischoff teaches a DNA SEQ ID NO: 1 (columns 30-34). A single base of Fishchoff's SEQ ID NO: 1 anticipates the claimed invention (claim 53 (c)).

Accordingly, Fischhoff anticipates the claimed invention.

15. Claim 71 is rejected under 35 U.S.C. 102(b) as being anticipated by Poovaiah, et al, US 5,498,533, issued 12 March 1996. Poovaiah teaches a plant transgenic for a DNA sequence (Poovaiah's SEQ ID NO: 1) which has 29 contiguous nucleotides identical to the SEQ ID NO: 1 of the claimed invention.

Accordingly, Poovaiah anticipates the claimed invention.

Remarks

16. No claim is allowed.

17. SEQ ID NO: 1 and 2 are free of the prior art.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer PhD
Patent Examiner
Art Unit 1638
November 16, 2002

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600